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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,668

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Lori N. Cross

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11/27/2009

SHOOK, HARDY & BACON L.L.P.

Intellectual Property Department

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EXAMINER

LUBIN, VALERIE

ART UNIT

PAPER NUMBER

3626

MAIL DATE

DELIVERY MODE

11/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/730,668

Applicant(s)

CROSS ET AL.

Examiner

VALERIE LUBIN

Art Unit

3626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7,8 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,8 and 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/14/09 has been entered.

2. Claims 1, 2, 5, 7, 8, 11-21 are pending

For reference purposes, the document paper number is 20091116

Response to Arguments

3. Applicant's arguments with respect to claims 1, 2, 5, 7, 8, 11-21 have been considered but are moot in view of the new ground(s) of rejection.

4. A rejection of claims 7, 8 and 11-21 under 35 USC § 101 is introduced, as the core processing steps of claims 7, 11 and 18, i.e. "analyzing", "comparing", and "identifying" are not tied to any apparatus.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 7, 8, 11-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

7. Based on Supreme Court precedent (See also *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) and recent Federal Circuit decisions, a §101 process must (1) be tied to a particular apparatus or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In addition, the tie to a particular apparatus, for example, cannot be mere extra-solution activity. See *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps.

To meet prong (1), the method step should positively recite the machine that accomplishes the method steps. Alternatively or to meet prong (2), the method step should positively recite identifying the material that is being changed to a different state or positively recite the subject matter that is being transformed.

In this case, the core processing steps of claims 7, 11 and 18, i.e. "analyzing", "comparing", "identifying" and "generating" are not tied to any apparatus. The claim limitations should positively recite the device of apparatus performing the steps.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 2, 5, 7, 8, 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner, U.S Patent No. 6,092,102 in view of Menschik et al., U.S. Pre-Grant Pub No. 2004/0034550 further in view of Zakim U.S. Patent No. 7,379,885

10. With respect to claim 1, Wagner discloses a system comprising a laboratory system data store (Col. 7 lines 15-24); a result posting module to post laboratory results and a callback module to identify a clinical laboratory result requiring a communication to the person placing the laboratory order based on comparison to certain conditions/criteria and clinical data (Col. 3 lines 47-56; col. 7 lines 38-52, col. 8 lines 23-34).

Wagner does not specifically recite identifying a result based on information about the clinical laboratory order, however, a predictable result of his invention would be to include as many relevant triggering events or data patterns (e.g. clinical order data) in the event monitor in order to generate more specific or custom message types (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Wagner recites a data-reception sub-system receiving information from an LIS (col. 7 lines 22-29) and posting lab results to a database (Col. 7 lines 38-45). Wagner does not disclose that the database is an electronic medical record (EMR) data store and the result posting module publishing the clinical laboratory results directly from the laboratory information system data store to the electronic medical records data store. However, Menschik recites and electronic medical records (Fig. 7, ¶ 90, 94). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Wagner with those of Menschik in order to facilitate medical data transfer among systems.

Wagner discloses an identified lab result being communicating to a recipient (Col. 7 lines 38-52) and Menschik recite an EMR communicating with users through a network (Fig. 3). Wagner and Menschik do not specifically disclose communicating lab results directly from the EMR to the person placing the lab order; however Zakim recites alerting a physician when a "significant medical fact is added by a laboratory to the patient's medical database" (Col. 30 lines 17-24). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Wagner, Menschik and Zakim in order to help physicians diagnose patient more efficiently.

Claims 5 and 7 are rejected under the analysis of claim 1.

11. Claim 2 is rendered obvious, as Menschik recites HL7 which is a standard data exchange interface (¶ 8).

Claim 8 is rejected under the analysis of claim 2.

12. With regards to claim 11, Wagner recites a method comprising the steps of accessing a data store containing a plurality of clinical laboratory results (Col. 7 lines 15-24); posting lab results to a database (Col. 7 lines 38-45); selectively identifying a clinical laboratory result requiring communication based on comparison to certain conditions/criteria and clinical data (Col. 7 lines 38-52, col. 8 lines 23-34); identifying a first preferred notification method (Col. 4 lines 53-57); and automatically generating a communication of the selected laboratory result by the first preferred method (Col. 7 lines 48-52).

Wagner does not specifically recite identifying a result based on information about the clinical laboratory order, however, a predictable result of his invention would be to include as many relevant triggering events or data patterns (e.g. clinical order data) in the event monitor in order to generate more specific or custom message types (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Wagner does not disclose an electronic medical record data store; however, Menschik recites and electronic medical records (Fig. 7, ¶ 90, 94). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Wagner with those of Menschik in order to facilitate medical data transfer among systems.

Wagner discloses an identified lab result being communicating to a recipient (Col. 7 lines 38-52) and Menschik recite an EMR communicating with users through a network (Fig. 3). Wagner and Menschik do not specifically disclose communicating lab results directly from

the EMR to the person placing the lab order; however Zakim recites alerting a physician when a “significant medical fact is added by a laboratory to the patient’s medical database” (Col. 30 lines 17-24). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Wagner, Menschik and Zakim in order to help physicians diagnose patient more efficiently.

13. For claim 12, Wagner recites determining if the communication of laboratory result is successfully completed (Col. 8 lines 52-59). Wagner also recites different communication channels (Abstract, col. 8 lines 8-22), and resending a message to a user (Col. 14 lines 38-46) and using an alternate route to resend a message (Col. 2 lines 41-42). It would therefore have been obvious to one of ordinary skill to use the teachings of Wagner to communicate message using an alternate communication channel in the event that a message fails to be communicated using a first channel in order ensure the relay of the message.

Claim 19 is rejected under the analysis of claim 12.

14. Regarding claims 13-17, Wagner recites selecting communication channels based on user preferences (Abstract). Another predictable result of Wagner would therefore be for such preferences to include conditions (e.g. communication device availability, user availability or schedule) and communication channels (e.g. email, PDA, telephone, etc.) that optimize the message delivery.

Claims 20 and 21 are also rejected under the above analysis.

15. With respect to claim 18, Wagner recites a method comprising the steps of accessing a data store containing a plurality of clinical laboratory results (Col. 7 lines 15-24); posting lab results to a database (Col. 7 lines 38-45); selectively identifying a clinical laboratory result requiring communication based on comparison to certain conditions/criteria and clinical data (Col. 7 lines 38-52, col. 8 lines 23-34); identifying a first preferred notification method (Col. 4 lines 53-57).

Wagner does not specifically recite identifying a number of conditions for the preferred method, but he does disclose prior art that recites testing a set of criteria, and based on such criteria being met, performing an action such as sending a message (Col. 2 lines 64-67; col. 3 lines 1-2). Furthermore, the step of automatically generating a communication of laboratory results if the conditions are satisfied is optional, and it has been held that, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation" (MPEP 2106.II C). Therefore, the last limitation of claim 18 does not further limit the claim.

Wagner does not disclose an electronic medical record data store; however, Menschik recites and electronic medical records (§ 90, 94). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Wagner with those of Menschik in order to facilitate medical data transfer among systems.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. L./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626